

NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Trade of Radioactive Material Practice

NRRC-SG-009



هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

2023

Stakeholder Guideline

Application for Authorization of Trade of Radioactive Material Practice
2023
NRRC-SG-009



Preamble

In accordance with the provisions of the NRRC's approved Regulations, this stakeholder guideline describes criteria and/or techniques that are considered appropriate for satisfying the requirements stipulated in the NRRC's regulations.

This stakeholder guideline has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, as well as the and the international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments, and it has been approved by the NRRC's CEO resolution No. 1409, dated 23/07/2023.



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1. Purpose

Nuclear and Radiological Regulatory Commission (NRRC) has developed an effective regulatory framework for the safe and secure authorization of trade / distribution of radioactive material practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within industrial radiography practice lies with the authorized person.

The purpose of this guideline document is to give the applicant and/or the authorized person clear and specific guidance on the submission for the purpose of trade / distribution of radioactive material practice authorization.

2. Scope

This guideline is addressed to trade / distribution of radioactive material facilities and activities, in particular, will address the management system, radiation protection, safety and security aspects of industrial radiography practice, including use, storage and transport. However, it is considered appropriate that a graded approach in the application of the requirements will be taken into account and should be adapted to the risks inherent to each facility.

This guideline includes the required information relating to radiation safety and security by the NRRC in order to verify the adequacy of the proposed safety and security measures as part of the authorization process.

This guideline applies for new authorization (License issuance), renewing the license as well as the license amendment.

3. Definitions

Assessment

The process, and the result, of analyzing systematically and evaluating the hazards associated with sources and practices, and associated protection and safety measures.

Quality Control (QC)

Part of quality management intended to verify that structures, systems and components correspond to predetermined requirements.

Source changer

A device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

Storage container

A container in which sealed sources are secured and stored.

Controlled area

A defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions, and preventing or limiting the extent of potential exposures.

Supervised area

A defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though specific protection measures or safety provisions are not normally needed.

4. Abbreviations

Abbreviation	Definition
NRRC	Nuclear and Radiological Regulatory Commission
RPP	Radiation Protection Program.
RSO	Radiation Safety Officer.
QC	Quality Control
SP	Security Plan
QA	Quality assurance

5. General and Administrative Information

The applicant should fill and sign the application form.

6. Integrated Management System

6.1. Management structure and responsibilities

- Description for the overall organizational and integrated management systems assuring that protection and safety and security are effectively incorporated into the overall management system of the applicant.
- Description of the responsibilities for radiation safety and security for the following parties as appropriate: RSO(s), person responsible for security, workers, outside workers, radiation safety committee and clients including responsibilities for cooperation and consultation.

- Positions with responsibility for regulatory matters, including any positions such as the licensee, radiation safety officer, security personnel, advisers, guards, and other security related positions specifically required by regulation. Provide an organization chart showing the staffing structure with lines of authority and supervision to demonstrate how the security organization and responsibilities fit within the overall site organization.

6.2. Description of regular assessment of protection, safety and security

The applicant should verify the compliance by Providing description of regular assessment of protection and safety and security such as Quality Assurance (QA) program and plans for regular reviews.

6.3. Confirmation of the procedures and programs

The applicant should Provide the following procedures and programs to the NRRC:

- Radiation source inventory, supply of sources, prior assessment of the radioactive sources and radiation generators and inventory of disused sources.
- Education, training and competence of the staff and their training, retraining, and informing.
- Investigation of incidents and accidents.
- Emergency preparedness and response.



- Control of modification(s) of facilities, equipment, and activity.
- Management of disused sources and depleted uranium if applicable.
- Safe transport.
- Import and export of radioactive sources.
- Control of visitors.
- Program for the improvement of the integrated management system.

7. Technical Information

7.1. Description of the exposure areas

- Description of the facility as follow:
 - A clear layout for the facility showing all the radioactive source storage, the radioactive waste storage, and adjacent areas, including the boundaries of controlled and supervised areas.
 - Specify in the layout shielding materials (concrete, lead, etc.) and means for securing radioactive materials from unauthorized removal.
 - Describe engineered safety systems e.g., area monitors, interlocks, alarms, etc. Include a description of the area(s) assigned for the receipt, storage, security, preparation, handling, waste storage and measurement of radioactive materials.

- Radiation survey report for the verification of the adequacy of installed shielding Demonstrate that doses are below dose constraints for workers and dose limit for members of the public.

7.2. Technical information of radiation monitoring equipment

The applicant should provide and demonstrate the following equipment:

- Portable radiation monitoring equipment
 - Specify technical information related to radiation monitors.
 - Demonstrate suitability and calibration of the monitor(s).
 - Provide the personnel monitoring devices.
- Personnel monitoring devices are provided to all workers
- Information on sealed or unsealed sources and provide periodical inventory to the NRRC
 - Radionuclide.
 - Manufacturer.
 - Chemical and physical form.
 - Packaging, including maximum activity per package.
 - Shielding provided to ensure that it is appropriate for safe handling and storage.



7.3. Sell and distribute sealed sources and devices for use in industrial gauges and radiographic operations

- Submit sufficient information relating to the design (identification of the radiographic exposure devices and source changers by manufacturer, model number, serial number, etc), prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the sealed source and device.
- Assure that each device bears a durable, legible, clearly visible label which contains:
 - Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating, and service manuals may be identified in the label and used to provide this information); and
 - The requirements for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, activity, and date of determination of the activity.
- Assure that a copy of the license or certificate of approval of the design of the sealed source/devices/source changers by the licensing authority of the country of origin should be submitted to NRRC as evidence of approval of the design.

7.4. Sell and/or Distribute Radiopharmaceuticals for Medical Use

- Assure that the radiopharmaceuticals meet the requirements imposed by NRRC.
- The label affixed to each package of the radiopharmaceutical should contain information of the radionuclide, activity, calibration date and time of assay.
- Procedures regarding assembling dispensing such as (hot cells information, shielding,)

7.5. Sell and/or Distribute Radioactive Materials for Certain In-Vitro Clinical or Laboratory Testing

- Assure that the package containing the radioactive material should bear a clearly visible label:
 - Identifying the radioactive contents as to chemical form, activity, and radionuclide.
 - Displaying the radiation caution symbol and the words “caution, radioactive material” and “not for internal OR external use in humans or animals”, as appropriate.
- Assure that the label affixed to the package or the leaflet or brochure which accompanies the package should contain adequate information as to the precautions to be observed in handling and storing such radioactive material and that the radioactive material will be used only for in-vitro clinical or laboratory tests not involving internal or external use of the material to human beings or animals.



7.6. Sell and/or Distribute I-131 Generators

- Workers are subject to I-131 exposure tests regularly.
- Assure that the label affixed to the generator contains information on the radionuclide, activity, and date of assay.
- Assure that the leaflet or brochure which accompanies the generator contains adequate information on the procedures to be followed and on the equipment and shielding to be used with the generator.
- Assure that a copy of a license or certificate of approval of the generator by the licensing authority of the country of origin should be submitted to NRRRC as evidence of approval of the design.

7.7. Sell and/or Distribute Sealed Sources and Devices for Medical Use in Brachytherapy

- Submit sufficient information regarding each type of source and device relevant to an evaluation of its radiation safety, including:
- Details of design and construction of the source and device.
- Procedures for, and results of, prototype tests to demonstrate that the source and device will maintain its integrity under normal use and accident conditions.
- Details of quality control procedures to assure that production of sources and devices meet the standards of the design and prototype tests.

- Procedures and standards for calibrating sources and devices; and
- Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the device or attached to a storage container for the source or device: Provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.
- Assure that the label affixed to the device containing the source, or to the storage container for the source or device, contains information on the radionuclide, activity, and date of assay.

7.8. Sell and Distribute Sealed Sources for Large Irradiators.

- Identify the manufacturer's name and model number of the gamma irradiator in which the sealed sources will be housed; and
- Specify the purpose for which the licensed material will be used (e.g., food irradiation, etc.), the location where it will be used and the prospective users.

7.9. Sell and/or Distribute Check, Reference, and Calibration Sources.

- Specify as to what categories of licensees the check, calibration or reference sources will be used.



- Ensure that the check, reference, or calibration sources have been obtained from a manufacturer authorized to sell/distribute the sources.
- Ensure that the manufacturer's labelling and packaging will not be altered and that the sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet brochure, or other document that provides radiation safety instructions for handling and storing the sources.

8. Safety Assessment

8.1. The safety assessment main elements

- Expected doses (occupational, public) arising from normal operation of the practice.
- Estimation of the potential doses (occupational, public) from anticipated operational occurrences and accident conditions (failures or internal or external events have occurred that challenge the safety of the facility or activity).
- Identification of postulated accident initiating events, commensurate with the features of the practice.
- Description of the severity of the potential consequences for workers and members of the public and associated with each of the accident initiating events. Provide the evaluation of the consequences for workers and members of the public based on the potential effect which each accident initiating event

could have without taking into account the safety measures or barriers envisaged.

- Description, for each accident initiating event, of the existing safety barriers to prevent or mitigate accidents.
- The risks associated with each accident initiating event. Risk needs to be expressed as a function of the frequency with which the initiating event occurs, the robustness of the safety barriers and the severity of the potential consequences associated with each initiating event. Risk may be classified following a prioritization principle to facilitate further decision making.
- Conclusions. Include a program of safety measures to be carried out for higher-risk initiating events to ensure the optimization of protection to the highest reasonably achievable safety level.
- Independent verification. Attach the results of independent verification of the safety assessment.
- Review of safety assessment. Demonstrate that regular and documented reviewing of safety assessment is in place.
- Demonstrate to the NRRC how the design of the calibration laboratory and the related operational procedures will contribute to the prevention of accidents or to the mitigation of the effects of accidents. This information should be provided in the form of a documented safety assessment describing and evaluating the predicted response of the plant



to incidents (including postulated malfunctions or failures of equipment, common cause failures and human errors) and external events that could lead to accident conditions.

8.2. The safety assessment consideration

These analyses should include consideration of combinations of such malfunctions, failures, errors, and events. Issues to be examined in the safety assessment include:

- Loss of access control.
- Malfunctions and failures of structures, systems, and components.
- Loss of control over the system for the movement of radioactive sources, including a source rack becoming stuck in the unshielded position.
- Loss of integrity of systems or components, including shielding integrity, encapsulation of sealed sources.
- Electrical distribution faults, from localized faults to complete loss of external energy sources.
- Failures of safety systems caused by fires within the facility.
- Failures of safety systems resulting from external causes such as storms, floods, earthquakes, or explosions.
- Failures of personnel to observe proper, safe procedures (for whatever reasons).
- Breakdown of procedures for preventing access to the facility by unauthorized persons.

- Breakdown of administrative procedures, leading to unsafe practices.
- Detection of contamination.
- High radiation levels in locations where high levels would not be expected.

9. Radiation Protection Program

The applicant should provide radiation protection program as follow:

9.1. Protection of Workers

- Personal dosimetry.
 - Specify and provide the personnel dosimetry service and arrangements related to monitoring of personal doses.
 - Provide the results of the review on past occupational doses.
 - Provide workers' (including outside workers) records of past occupational exposure if not already recorded in the registry of occupational doses.
 - Education and training of workers.
- Workers' health surveillance.
 - The applicant should specify programs for health surveillance.
- Education and training of workers.
 - Specify names, qualification, education, training, and re-training.



- Describe how staff (including assistants and trainees) are trained and qualified.
- Outside workers (if applicable).
 - Describe the allocation and documentation of the responsibilities of the employer and the applicant for safety and protection of outside workers.
- Female workers.
 - The applicant should describe the procedure for the employer notification on pregnancy for female worker.
- Persons under 18.
 - The applicant should guarantee that no person under the age of 16 years is or could be subject to occupational exposure. While probably unlikely, a trainee operator aged 16 to 18 years could commence training under supervision to become an operator of an inspection device.
- Arrangements for the Radiation Protection Program (RPP).

The applicant should demonstrate that all elements of the RPP are in place, e.g., provide a copy of a RPP:

 - Assignment of responsibilities for the RPP.
 - Designation of controlled areas or supervised areas.
 - The applicant should specify designation of controlled and supervised area using safety assessment and measured dose rates at working room(s)/area(s), storages(s).
 - The applicant should demonstrate appropriate managing of labels, marks, and notices.

- Practice specific local rules.
 - Demonstrate that local rules applicable for workers are prepared for all processes of the applicant and that an adequate number of workers is involved in the practice.
 - Specify roles and responsibilities as well as demonstrate that supervision of processes is taking place.
 - Demonstrate that rules, labels, and marks are in a language understood by those for whom they are intended.
 - Demonstrate that the necessary amount of radiation monitoring equipment is available and specify their technical specification, selection, calibration, maintenance, testing and use of radiation monitoring equipment.
 - Demonstrate that monitoring program take into account all processes of the applicant, e.g., use and maintenance of radiation equipment, accepting packages with new radioactive sources and preparing packages for transport.
 - Demonstrate that appropriate personal protective equipment is provided, and arrangements are made for its proper use, testing and maintenance.
- Record and reporting of information.
 - The applicant should describe the system for recording and reporting all information related to exposure control, decisions regarding measures for occupational radiation protection and safety as well as individual radiation monitoring.



- **Audit and review of the RPP**
 - The applicant should specify the methods for periodic auditing and review of implementation of the RPP.
- **Information on workers:**
 - Should be properly trained and qualified, and they should be competent.
 - Should follow the local rules and other relevant procedures.
 - Should use calibrated workplace monitoring instruments and wear suitable personal dosimeters before.
 - Should undertake regular and appropriate inspections of the trade of radioactive materials process.
 - Should make proper use of emergency equipment.
 - Should conduct a final survey of the trade of radioactive materials process before leaving.

9.2. Protection of the Public

- **Procedures of protection and safety to protect members of the public:**
 - Describe the procedure of protection and safety to protect members of the public.
 - Demonstrate that optimization of radiation protection of public is in place.

- Demonstrate that assessment, control, and surveillance of external exposure of public are in place, i.e., use of dose constraints for the member of the public. Provide assumptions used to assess external exposure of public.
- Describe training of personnel having functions relevant to protection and safety of members of the public. Demonstrate that monitoring program and management of records are in place.
- Describe the use of signs, labels, marks, and notices to be noticed by members of the public. Confirm that they are in a language to be understood by members of the public.

10. Emergency Preparedness and Response Plan

10.1. Emergency Equipment

For emergencies involving trade of radioactive materials, provide details description about allocation of the following equipment, as appropriate:

- Appropriate monitoring instruments to measure both high and low dose rates where the trade of radioactive materials will be performed.
- Active personal alarm dosimeters.
- Additional personal dosimeters.
- Local shielding, such as bags of lead shot or lead sheets.
- Suitable tool kits and source recovery equipment (long handled tongs, pliers, screwdrivers, bolt cutters, adjustable spanner).



- A spare shielded container.
- Wipe test kit for leak testing sources and for other surface contamination checks.
- Communication equipment.
- Spare batteries and torches.

10.2. Type of Emergency

Provide information on incidents involving trade of radioactive materials have included but not limited to the following:

- Damage to trade of radioactive materials equipment.
- Loss of shielding resulting in higher dose rates than expected.
- Missing (or lost) radioactive sources.
- Dropped or detached sources.
- Leaking sources due to impact of the used equipment.
- Natural disasters.
- Malicious acts such as theft of sources.

10.3. Information on workers

- Identification should be properly trained and qualified, and they should be competent.
- Should follow the local rules and other relevant procedures.

- Should use calibrated workplace monitoring instruments and wear suitable personal dosimeters before.
- Should undertake regular and appropriate inspections of the trade of radioactive materials process.
- Should make proper use of emergency equipment.
- Should conduct a final survey of the trade of radioactive materials process before leaving.

Identification of all persons and organizations who will be contacted as necessary at the various stages of the plan, as well as the relevant telephone numbers, fax numbers and email addresses.

11. Records, Reports and Notification.

11.1. The content of Records, reports and notification.

The applicant should provide the Records, reports and notification that should include the following:

- Records of Radiation Safety Program.
- Records of Personnel Monitoring.
- Records of Surveys.
- Records of Disposition of Sealed Sources.
- Records and Reports of Sale, Distribution, and/or Transfer of Radioactive Material.



11.2. Records submission to NRRC

These records should be submitted to NRRC on semi-annual basis. The records must include at least the following information:

- The radionuclide/s.
- The activity and its determination date.
- Information on the physical state of the radioactive material.
- The consignee of the radioactive material and its NRRC license number.
- The manufacturer of the radioactive material.
- The unique serial number of the radioactive material if it is a sealed.
- Reports of Theft or Loss of Radioactive Material.
- Emergency report.

11.3. Emergency Reporting

The report on an emergency should include the following:

- A description of the emergency, with as much detail as possible of the equipment involved.
- Environmental conditions at the time of the emergency, with reference to whether these conditions played any significant part in causing the emergency or affecting the outcome.
- The specific cause(s) of the emergency.
- Details of actions taken to regain control of the situation and

to restore conditions to normal, with special reference to any actions that were notably beneficial or detrimental.

- The personnel involved and their duties, tasks, and qualifications.
- An assessment and summary of the doses received by all affected individuals.
- Corrective actions recommended with the aim of preventing similar emergencies in the future.
- Lessons from managing the emergency.
- Notification of Incidents.
- Notification on Specific Changes in the License.



12. Related documents and files

Document Name	Document Type	Document Number	Relation to the guideline
Radiation Safety	Technical Regulation	NRRC-R-01	This Regulation set out the general safety requirements in ensuring protection of people and the environment against the harmful effects of ionizing radiation and for the safety of radiation sources.in addition, this regulation harmonize the requirements applicable in the Kingdom with the international best practices in order to achieve the highest standards of safety in activities and facilities that give rise to radiation risks
Notification on and Authorization of Facilities and Activities with Radiation Sources	Technical Regulation	NRRC-R-02	Prescribes the general requirements for notification on and authorization of activities, facilities and practices with radiation source, nuclear material and/or ore containing uranium and thorium in the Kingdom

<p>Safe Transport of Radioactive Materials</p>	<p>Technical Regulation</p>	<p>NRRC-R-15</p>	<p>This regulation is to pre- scribe requirements that shall be fulfilled to ensure safety, security and to protect persons, property, and the environment from any harm- ful effects of radiation on the transport of radioactive ma- terials or nuclear material.</p>
<p>Management of Radioactive Waste</p>	<p>Technical Regulation</p>	<p>NRRC-R-16</p>	<p>This regulation sets out the safety objectives, criteria and requirements for the protec- tion of human health and the environment that shall be applied to the activities and the requirements that shall be met to ensure the safety of such activities and facilities.</p>
<p>Security of Radioactive Material</p>	<p>Technical Regulation</p>	<p>NRRC-R-17</p>	<p>This regulation that ad- dressed security of radioac- tive material, associated ac- tivity, and associated facility against unauthorized remov- al of radioactive material and sabotage performed with the intent to cause harmful ra- diological consequences</p>

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